IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Carnazza, James A.
Application Number	:	10/654,850
Filing Date	:	September 04, 2003
Title	:	Methods For Testing For And Inhibiting The Development Of Huntington's Disease
Attorney Docket No.	:	18184-00001
Examiner	:	Daniel E. Kolker
Group Art Unit	:	1649

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AMENDMENT AND RESPONSE

This Amendment and Response, accompanied by a Request for Continued Examination, is being filed in response to the Office Action dated June 8, 2006 finally rejecting all pending claims. A one-month extension of time is requested. Please charge Deposit Account 50-1582 for the fees due for the one-month extension of time and the Request for Continued Examination; credit any overpayment of fees to 50-1582. The Applicant respectfully requests entry of the present amendments and reconsideration.

Amendments to the Claims are reflected in the listing of claims that begins on page 2 of this paper.

Remarks/Arguments begin on page 5 of this paper.

Amendments to the Claims:

The following listing of claims replaces all prior versions and listings of claims in the application.

Listing of Claims

1. (Currently amended) A method for ~~regulating estrogen levels~~ assaying the number of glutamine repeats in the huntingtin protein of [in] an individual ~~who carries the Huntington's disease gene~~, comprising the steps of:

providing aliquots of at least two recombinant huntingtin proteins having different known numbers of glutamine repeats;

providing an aliquot of huntingtin protein obtained from the individual having a number of glutamine repeats to be determined;

contacting the aliquots of the recombinant huntingtin proteins and the aliquot of huntingtin protein obtained from the individual with a steroid hormone having a detectable label;

detecting the amount of binding of the steroid hormone to the recombinant huntingtin proteins having different known numbers of glutamine repeats;

detecting the amount of binding of the steroid hormone to the huntingtin protein obtained from the individual having a number of glutamine repeats to be determined; and

determining the a number of glutamine repeats as indicated by the amount of binding of the steroid hormone to the huntingtin protein obtained from the individual by comparison to the amount of binding of the steroid hormone to the recombinant huntingtin proteins having different known numbers of glutamine repeats, thereby assaying the number of glutamine repeats in the huntingtin protein of an individual.

~~determining that the individual exhibits a trinucleotide repeat pattern, consisting of cytosine, adenine, and guanine (CAG), that comprises at least 38 CAG repeats;~~

~~determining the affinity of estradiol to bind to a polyglutamine located at an end of a huntingtin polyglutamine protein to determine an optimum time to begin regulating estrogen levels of said individual;~~

~~establishing that a serum level of estrogen in said individual is below normal for that individual;~~

~~administering one or more estrogen compounds, selected from a group consisting of estrogen, estrogen's respective precursors, and esters of estrogen, in amounts sufficient to maintain estrogen at a level normal for that individual~~.

2-6. (Canceled)

7. (Currently amended) The method of claim 1, wherein the steroid hormone is selected from the group consisting of estrogen, estrogen precursors, estrogen esters, and esters of estrogen precursors. ~~said predetermining step comprises the steps of,~~

~~obtaining one or more samples of a huntingtin polyglutamine protein with known numbers of glutamines;~~

~~mixing said sample with a labeled estradiol source and a buffering solution;~~

~~measuring the binding affinity of the labeled estradiol source to the huntingtin polyglutamine protein.~~

8. (Currently amended) The method of claim 1, wherein the detectable label is a radioactive label. ~~said affinity is measured with a gamma counter and is equal to or less than about 50,000 counts per minute.~~

9-12. (Canceled)

13. (Currently amended) The method of claim 1, wherein the recombinant huntingtin proteins have about 23 to about 63 glutamine repeats.

~~A method of regulating certain hormone levels in an individual who carries the Huntington's disease gene, comprising the steps of:~~

~~determining that the individual exhibits a trinucleotide repeat pattern, consisting of cytosine, adenine, and guanine (CAG), that comprises at least 38 CAG;~~

~~determining the affinity of estradiol to bind to a polyglutamine located at an end of a huntingtin polyglutamine protein to determine an optimum time to begin regulating estrogen levels of said individual;~~

~~establishing that a serum level of one or more hormone compounds, selected from a group consisting of estrogen, testosterone, progesterone, and their respective precursors, in said individual is below normal for that individual; and~~

~~administering one or more of said hormone compounds or an ester of said one or more of said hormone compounds to maintain said hormone compounds at a level normal for that individual~~.

REMARKS

Claims 1, 7, 8, and 13 are pending. Claims 1, 7, 8, and 13 are amended. Support for the amendments to the claims can be found in the specification and claims as filed, and at least at page 9, line 10 to page 11, line 19. No new matter has been added.

Oath/Declaration

A new Declaration (PTO/SB/01) was presented in the papers filed September 8, 2006.

Support for the Claimed Invention in the Provisional Patent Applications

Applicant respectfully traverses the Examiner's determination that the provisional applications do not provide support for the presently claimed invention. The present amended claims are directed towards a method for assaying the number of glutamine repeats in the huntingtin protein of an individual by a method having steps that include contacting an aliquot of huntingtin protein obtained from the individual with a steroid hormone having a detectable label, where the steroid hormone is selected from the group consisting of estrogen, estrogen precursors, estrogen esters, and esters of estrogen precursors, and determining the number of glutamine repeats as indicated by the amount of binding of the steroid hormone to the huntingtin protein obtained from the individual by comparison to the amount of binding of the steroid hormone to recombinant huntingtin protein standards having different known numbers of glutamine repeats, thereby assaying the number of glutamine repeats in the huntingtin protein of an individual.

The provisional patent applications disclose that whether an individual has inherited the HD gene that leads to the development of the disease can be determined by a direct gene test using blood samples, where the genetic test counts the number of CAG repeats in the HD gene region. One of ordinary skill knows that CAG encodes the amino acid glutamine, and CAG repeats encode polyglutamine. The provisional patent applications further disclose that steroid hormones binding to the polyglutamine located on the end of the huntington protein to prevent the protein from inducing cell death, and that the length of the polyglutamine determines the level of estrogen needed to render the protein ineffective in causing cell death.

Support can be found in U.S. Provisional Patent Application No. 60/408,184 filed September 4, 2002 on page two, the first two sentences of the paragraph spanning pages 2 and 3; and page 5: "In this case estrogen binds to the polyglutamine located at the end of the huntington protein," and " . . .the length of the CAG polyglutamate [sic] repeat determines the level of estrogen needed to render this protein ineffective in causing cell death . . ." Support can be found in U.S. Provisional Patent Application No. 60/443,397 filed January 29,2003 on page two, the first two sentences of the paragraph spanning pages 2 and 3; and page 5: "In this case estrogen, testosterone and/or their precursors bind to the polyglutamine located at the end of the huntingtin protein," and " . . .the length of the CAG polyglutamate [sic] repeat determines the level of estrogen needed to render this protein ineffective in causing cell death . . ."

Claim Rejections

Claim Rejection Under 35 U.S.C. § 112, First Paragraph, Enablement

Claims 1, 7, 8, and 13 stand rejected under 35 U.S.C. § 112, first paragraph. The Office Action dated June 8, 2006 states that the specification "while being enabling for determining whether or not estrogen binds to huntingtin protein *in vitro*, does not reasonably provide enablement for regulating estrogen . . .." The currently amended claims are directed to *in vitro* measurements of the binding of detectably labeled steroid hormones, such as estrogen, to huntingtin protein. Applicant respectfully requests that this rejection be withdrawn.

Claim Rejection Under 35 U.S.C. § 112, First Paragraph, Written Description

Claims 1, 7, 8, and 13 stand rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. The Applicant submits that this rejection is moot in view of the present amendments to the claims. Applicant respectfully requests that this rejection be withdrawn.

Claim Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 1, 7, 8, and 13 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Applicant submits that this rejection is moot in view of

the present amendments to the claims. Applicant respectfully requests that this rejection be withdrawn.

CONCLUSION

In light of the amendments and arguments presented herein, the Applicant respectfully requests reconsideration and a timely Notice of Allowance to follow in this case. The Applicant requests that the Examiner telephone the undersigned at (508) 929-1658 in the event a telephone discussion would be helpful in advancing the prosecution of the present case.

Respectfully submitted,

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